



# Corrective and Preventive Action

**FDA Small Business  
Regulatory Education for Industry (REdI)**  
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# Objectives

- Discuss purpose of Corrective and Preventative Action and provide definitions
- Identify Quality System (QS) Regulation requirements and GHTF Guidance
- Discuss various types of data and tools
- Provide examples
- Identify compliance concerns

# **Purpose of the Corrective and Preventive Action Subsystem**

- To collect and analyze information to identify actual and potential product and quality problems
- To investigate product and quality problems and take appropriate and effective corrective or preventive action
- To verify or validate the effectiveness of corrective and preventive actions

# **Purpose of the Corrective and Preventive Action Subsystem**

- To communicate corrective and preventive actions to the appropriate people
- To provide information for management review
- To document activities

# Definition: Correction

- **“Correction”** action to **eliminate** a detected **nonconformity**.
  1. A correction can be made in conjunction with a corrective action.
  2. A correction can be, for example, rework or regrade

ISO 9000:2005(E)

# Definition: Corrective Action

- **“Corrective action”** action to **eliminate the cause** of a detected non-conformity or other undesirable situation.
  1. There can be more than one cause for a nonconformity.
  2. Corrective action is taken to prevent recurrence.
  3. There is a difference between correction and corrective action.

*ISO 9000:2005(E)*

# Definition: Preventive Action

- **“Preventive action”** action to **eliminate** the cause of a ***potential*** non-conformity or other undesirable situation
  1. There can be more than one cause for a potential nonconformity.
  2. Preventive action is taken to prevent occurrence.

*ISO 9000:2005(E)*

# U.S. Regulatory Requirement - Procedures

- Establish and maintain procedures for implementing corrective and preventive action

*21 CFR 820.100(a)*



# The Preamble on Procedures

- The procedures (for implementing corrective and preventive action) must provide for control and action to be taken on devices distributed, and those not yet distributed, that are suspected of having potential nonconformities.

*Preamble, Comment 158*

# Guidance Available

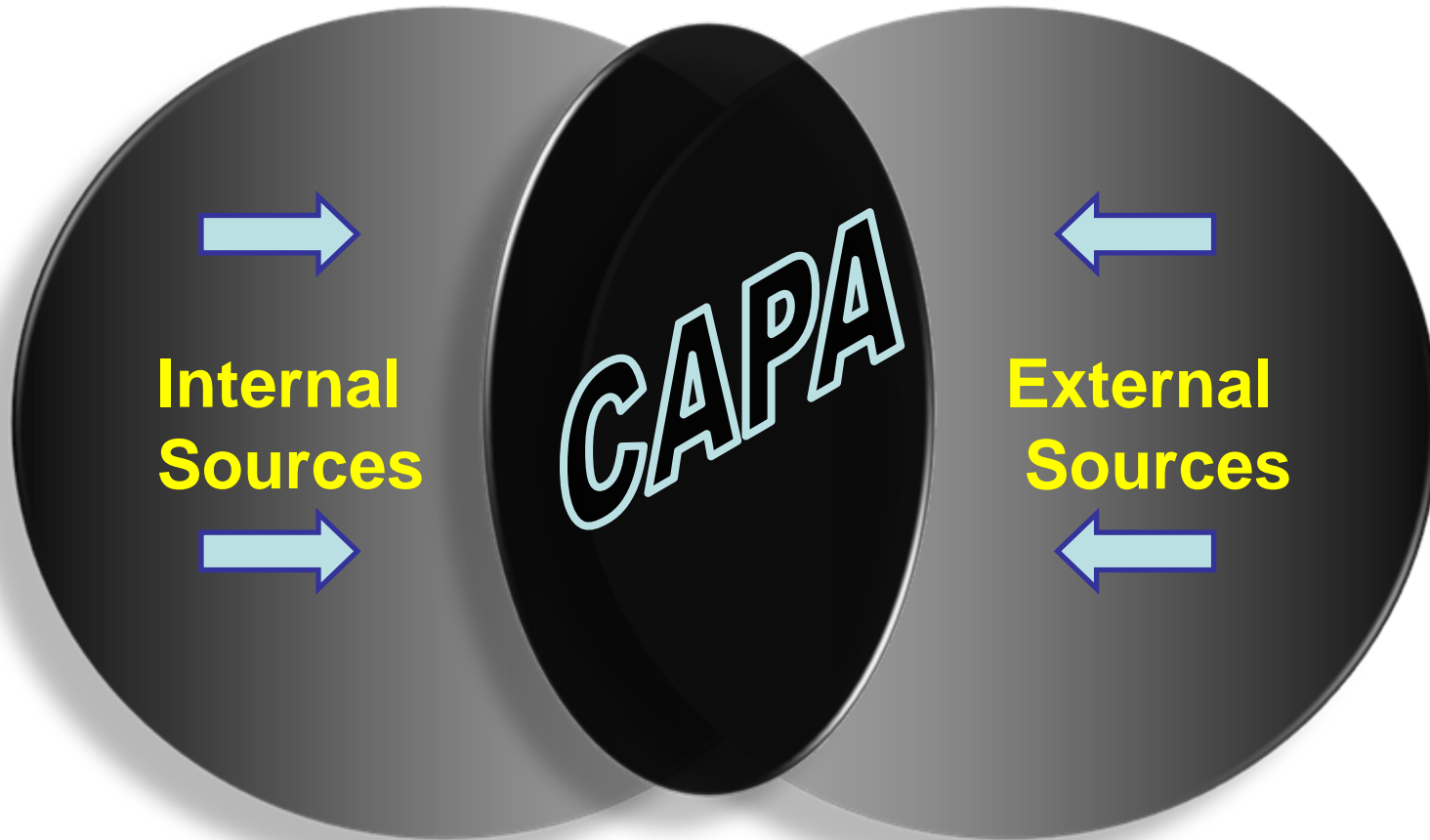
- GHTF: Quality Management System  
Medical Devices – Guidance on corrective action and preventive action and related QMS processes; SG3; 2010
- GHTF: Quality Management System  
Medical devices - Nonconformity Grading System for Regulatory Purposes and Information Exchange; SG3; 2012

# Where to Start? Planning

Plans should include...

- I. Establishing Data Sources and Criteria
- II. Measuring and Analysis of Data Sources
- III. Improvement Plans
- IV. Input to Management

# Establishing Data Sources



# Examples of Internal Data Sources

- Process Control Data
- Test/Inspection data
- Device History Records
- Internal Audits
- Nonconforming material reports
- Scrap/Yield Data
- Rework
- Training records

# Examples of External Data Sources

- Supplier Controls
- Customers
- Complaints
- Product Warranty repairs
- Adverse Event Reporting (MDR)
- FDA
- Even similar devices from competitors

# Data Analysis

- Analyze processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems.

*21 CFR 820.100(a)(1)*

# **Approach to Data Analysis**

## **Non-statistical & Statistical Techniques**

- **Use a risk-based approach to rank areas**  
Select items with major impact, i.e. Product related or Process related  
Proceed with items from high to low impact and eventually assure all areas are addressed
- **Use of Statistical Methodology**  
CFR 820.100(a)(1) Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems



# Investigate to Determine Root Cause

- Investigate the cause of nonconformities relating to product, processes, and the quality system

*21 CFR 820.100(a)(2)*

# The Preamble on Investigations

- The requirement in this section is broader than the requirement for investigations under Sec. 820.198, because it requires that nonconforming product discovered before or after distribution be investigated to the degree commensurate with the significance and risk of the nonconformity.

*More . . .*

# The Preamble on Investigations

- ...the requirement in this section applies to process and quality system nonconformities, as well as product nonconformities...if a molding process with its known capabilities has a normal 5 percent rejection rate and that rate rises to 10 percent, an investigation into the nonconformance of the process must be performed.

*Preamble, Comment 161*

# Identify Corrective and Preventive Actions

- Identify the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems

*21 CFR 820.100(a)(3)*

## **Identify Action(s) to be taken**

- No further action necessary
- Correction
- Corrective Action
- Preventative Action

# The Preamble on Risk and Degree of Corrective and Preventive Action

- ...the degree of corrective and preventive action taken to eliminate or minimize actual or potential nonconformities must be appropriate to the magnitude of the problem and commensurate with the risks encountered. . .

*Preamble, Comment 159*

# Verify/Validate Corrective and Preventive Actions

- Verify or validate the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device

*21 CFR 820.100(a)(4)*

# The Preamble on Verification and Validation

- FDA has revised Sec. 820.100(a)(4) to reflect that preventive, as well as corrective, action must be verified or validated.

*Preamble, Comment 163*

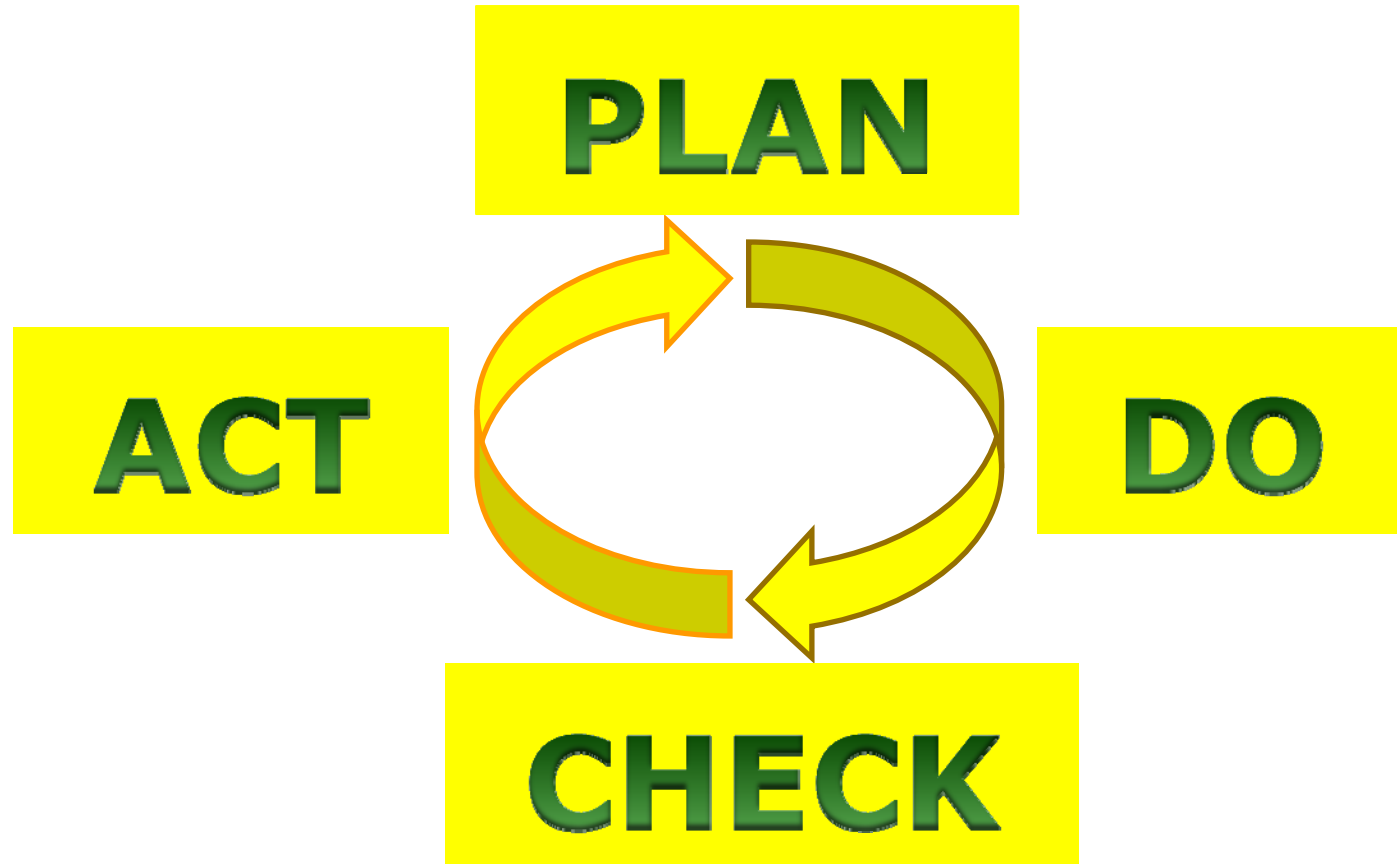


# Implement Corrective and Preventive Actions

- Implement and record changes in methods and procedures needed to correct and prevent identified quality problems

*21 CFR 820.100(a)(5)*

# Close the Loop



# Communicating CAPA Information

- Disseminate information related to quality problems or nonconforming products to those directly responsible for assuring the quality of such product or the prevention of such problems. *21 CFR 820.100(a)(6)*
- Submit relevant information on identified quality problems, as well as corrective and preventive actions, for management review. *21 CFR 820.100(a)(7)*

## The Preamble on CAPA Activities for Management Review

- . . . Only certain information need be directed to management. The manufacturer's procedures should clearly define the criteria to be followed to determine what information will be considered "relevant" to the action taken and why. FDA emphasizes that it is always management's responsibility to ensure that all nonconformity issues are handled appropriately.

*Preamble, Comment 164*

# Documenting Corrective Action and Preventative Action Activities

- Document all activities required under this section, and their results

*21 CFR 820.100(b)*

# The Preamble on CAPA and Internal Audits and Mgmt Reviews

- Two comments stated that the records required under Sec 820.100(b) should be treated as part of the internal audit. FDA disagrees with these comments...FDA has the authority to review such records and the obligation to do so to protect the public health. . . Manufacturers will be required to make this information readily available to an FDA investigator

*Preamble, comments 166*

# FDA Inspection

- Manufacturers should consider that their Corrective Action and Preventative Action documentation can demonstrate to FDA that the manufacturer's quality system is effective and enables them to identify problems quickly and implement effective corrective and preventive actions

# 2011 FDA Inspectional Data

## FDA 483 Observations

- Source of data - FDA's Turbo EIR database
- Time frame 1/1/2011 to 12/31/2011
- **3995** observations cited for 21 CFR 820 deficiencies out of **3153** inspections
- **1184** observations cited for Corrective and Preventative Action Subsystem. Second to Production and Process Controls, 31% verse 30% of all observations cited.



# CAPA Subsystem Warning Letter Data

Year	# w/ CAPA cite	%
<b>2011</b>	<b>104</b>	<b>85%</b>
2010	81	91
2009	68	88
2008	86	88
2007	62	84
2006	69	87
2005	85	88
2004	89	79

# Most Frequent QS Warning Letter Cites 2011

- **CFR 21 820.100 (a)** **55**
- **CFR 21 820.198 (a)** **47**
- CFR 21 820.22 39
- CFR 21 820.30 (g) 34
- **CFR 21 820.90 (a)** **32**
- CFR 21 820.30 (i) 27
- CFR 21 820.75 (a) 26
- CFR 21 820.50 26
- CFR 21 820.20 (c) 24
- CFR 21 820.184 23

# Additional FDA Guidance Available On Our Website

- Compliance Program Guidance Manual for Inspection of Medical Device Manufacturers (CP 7382.845)
- QSIT:  
<http://www.fda.gov/ICECI/Inspections/InspectionGuides/ucm074883.htm>

**THANK YOU**

